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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,514	02/11/2004	Kerry Zang	073275.0163	5263
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BAKER BOTTS L.L.P. 2001 ROSS AVENUE SUITE 600 DALLAS, TX 75201-2980			EXAMINER MILLER, CHERYL L	
			ART UNIT 3738	PAPER NUMBER
			NOTIFICATION DATE 07/21/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/777,514

Applicant(s)

ZANG ET AL.

Examiner

CHERYL MILLER

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-44, 46-57, 62, 63 and 65-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-44, 46-57, 62, 63 and 65-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 April 2008 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 40-44, 46-57, 62, 63, and 65-70 have been considered but are moot in view of the new ground(s) of rejection.

The applicant has argued that Bailey (US 5,607,304) does not disclose a thread having a leading and trailing flank. The examiner disagrees. See figure 3, wherein the thread (22) has a leading flank (38) inclined away from a second end (bottom end) and a second flank (36) inclined away from a first end (top end) and separated by a crest (37) having an angle (see fig.3). The applicant has also argued that Bailey does not disclose a body configured for precise fit into a sinus tarsi. The examiner disagrees. This is intended use language. The Bailey device has the capability of placement at such a location. Bailey's device is for implantation in bone of a human, thus has a relatively small dimension. Such a size and shape has the capability of fitting at such a location in the body.

The applicant has argued that Persoon's (US 5,683,460) does not disclose a leading and trailing flank. The examiner disagrees. Persoon's thread is shown in figure 2, the thread has a leading and trailing flank (each side of the thread) and a thread angle (angle seen in fig.2), the flanks extend away from the ends in the radial direction. The applicant has also argued that Persoon's device is not capable of precisely fitting in the sinus tarsi. The examiner disagrees. Persoon's device is for implantation into the body, as a spacer for between bones, thus it has the same function as applicants device. Further it must be small in size in order to fit in such locations, in fact the length and diameter dimension disclosed by Persoon's (col.5, lines 5-15) fall

within the disclosed dimensions of applicant, thus Persoon's device is inherently capable of a precise fit into the sinus tarsi, just as applicant's device is.

The applicant has argued that Crombie (US 5,961,524) does not disclose a device configured for precise fit into a sinus tarsi. The examiner disagrees. Crombie's device is for implantation into bone, thus is of a relatively small size. Further Crombie discloses a wide variety of taper angles, including that of applicant's device. Crombie's device is capable of such placement into a sinus tarsi and further is capable of a precise fit, as Crombie has disclosed a wide variety of possible dimensions.

The applicant has argued that Zdeblick (US 2004/0097928 A1) does not disclose a leading and trailing flank. The examiner disagrees. Thread 19 clearly has a thickness, and the two sides of the thread (19) are considered the "flanks". They are shown in figures 3 and 5 inclined away from the respective ends and they are separated by an angle (are angles toward one another).

Specification

The amendment filed April 28, 2008 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: each new recitation of substantially. Although applicant appears to have support for constant thread height and pitch, applicant does not appear to have support for the term "substantially" constant.

Applicant is required to cancel the new matter in the reply to this Office Action.

Drawings

The drawings (new fig.4) were received on April 28, 2008. These drawings are not acceptable. New figure 4 appears to be too different than figure 1. Applicant only has disclosed *one* embodiment of thread profile in the specification, which applicant has argued is a constant height and pitch profile. If indeed the thread profile is constant (height and pitch) as applicant has alleged, then it cannot also be varied (applicant has disclosed a varied size of a thread within a disclosed range, however has not disclosed a varied sized amongst the threads). Figure 4 is not accepted since it appears so different in size/shape than figure 1, too different to be considered the same embodiment. Reference made to a constant thread height and pitch should be made to figure 1, not added as a completely new figure that appears as a different embodiment. It is understood that figures are not to scale, thus a reference to figure 1 showing the height and pitch to be constant is sufficient (otherwise, by having both figure 1 and 4, they appear to be different embodiments, one constant and one varied, and applicant does not have support for both embodiments).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 40, 44, 46, 48, 55-57, 62-63, and 65-70 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 40, 44, 46, 48, 55, 67, and 70 each recite, “a *substantially* constant” thread height or pitch. Although applicant seems to have support for a constant thread height or pitch (support provided in original claim by applicant in response), applicant does not have support for the term “*substantially*” which broadens the dimension to a range such that adjacent threads may have slightly different dimensions.

Claims 40, 55, 67, and 70 each recite, “configured to *fit precisely* into a sinus tarsi”, which is considered new matter. Although the specification discloses that a tapered configuration will fit *more* precisely than a cylindrical configuration (*better* fit than an alternate shape), the implant does not have support for a precise fit (*perfect* fit). Claims 56-57, 62-63, 65-66, and 68-69 depend upon the above claims and inherit all problems with them.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 41-43, 46-54, 56-57, 62-63, and 65-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 41 has improper dependency, it may not depend upon itself. Claims 42-43, 46-54 depend upon claim 41 and inherit all problems associated with the claim.

Claims 41, 56, 67, and 70 each recite, “the leading flank separated by the trailing flank by a thread angle”. This limitation is indefinite and unclear. The flanks are separated by a distance, not an angle. It is the crest that has an angle, not the separation distance of the flanks. It is suggested to instead recite that the flanks are connected by the crest, wherein the crest has (or

forms) a thread angle. Claims 42-43, 46-54, 57, 62-66, and 68-69 depend upon the above claims and inherit all problems associated with them.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 40, 41, 52, 53, 55, 56, 62, and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by Bailey et al. (US 5,607,304, cited previously). Bailey discloses a medical implant (16; fig.1, 2) comprising a body (shaft portion of 16) configured for implantation and precise fit into the sinus tarsi (is capable of placement at such a location to fit between bones), the body (shaft of 16) comprising a first end (top of shaft where threads begin), a second end (bottom of shaft where threads end) and at least one continuous and uninterrupted thread (22) including a crest with a flat surface (37) and constant thread height (appears constant in figures; col.3, lines 2-7), the thread (22) helically traversing the length of an exterior surface of the body (threads span entire shaft portion of 16), the length spanning from the first to second end, a recessed engagement (at 23) in the first end and wherein a circumference of the exterior surface of the body tapers from the first end to the second end (see fig.2). Bailey has shown a body (shaft of 16) that is generally conical and appears to taper uniformly (see fig.2). Bailey discloses the thread having a leading and trailing flank inclined away from the ends (see embodiment in fig.3) and separated by a thread angle (fig.3).

Claims 40, 41, 47, 50, 52-56, 62, 63, 66, and 70 are rejected under 35 U.S.C. 102(b) as being anticipated by Persoon's (US 5,683,460, cited previously). Persoon's discloses a medical implant (101; fig.2) comprising a body (102) *configured* for implantation into the sinus tarsi for precise fit (is capable of placement at such a location and capable of such a fit as Persoon's device is relatively small and intended for use between bones to act as a spacer), the body (102) comprising a first end (108), a second end (104) and at least one continuous and uninterrupted thread (105) including a crest with a flat surface (see fig.2; col.3, lines 23-25) and constant thread height (appears constant in figs), the thread helically traversing the length of an exterior surface of the body (thread traverses entire length), the length spanning from the first to second end, a recessed engagement (recess or hollow; col.4, lines 2-3, 5-7; col.2, lines 7-8) in the first end and wherein a circumference of the exterior surface of the body tapers from the first end to the second end (see fig.2). Persoon's has shown a body (102) that is generally conical and appears to taper uniformly (see fig.2). Persoon's discloses a flat face on the first end (108) with a recess (col.4, lines 5-7) and flat face on the second end (104a; see fig.2) surrounding bore (hollow; col.4, lines 2-3; col.2, lines 7-8). Persoon's thread has a leading and trailing flank (sides of thread) inclined away from the ends (is inclined away in the radial direction, thus extends away from the ends) and has a thread angle (see figs).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 43, 46, 48, 49, 50, 51, and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey et al. (US 5,607,304, cited previously). Bailey discloses a medical implant and method of forming the implant substantially as claimed (see above) having what appears to be constant repeated threads (thus constant pitch and height). Bailey is silent however to mention specific dimensions of the threads (angle, pitch, height, root width). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the dimensions claimed, since wherein the general conditions are disclosed in the prior art (threads having a height, pitch, width, etc) it is not inventive to discover the optimum or workable ranges (dimensions claimed). *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Claims 40, 41, 43, 50, 52, 53, 55, 56, 62, and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crombie (US 5,961,524, cited in IDS). Crombie discloses a medical implant (10) comprising a body (entire screw 10) *configured* for implantation and fit into the sinus tarsi (is capable of placement at such a location and due to its disclosed wide variation of size/shape, it is capable of precise fit), the body comprising a first end (top of screw head), a second end (bottom of screw) and at least one continuous and uninterrupted thread (20) including a crest (22) having a constant thread height (col.4, lines 20-23), the thread (20) helically traversing the length of an exterior surface of the body (thread does traverse some of the length; it is noted to applicant that the thread is not required to traverse the *entire* length of the body), the length spanning from the first to second end (the length does span this distance-threads are not required to span this distance), a recessed engagement (24) in the first end (top of screw head) and wherein a circumference of the exterior surface of the body tapers from the first end to the

second end (see figs). Crombie disclose a leading and trailing flank (sides of thread) inclined away from the ends (see figs). Crombie discloses the medical implant substantially as claimed, however discloses a rounded crest instead of a flat crest as claimed. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a flat crest since although Crombie discloses a rounded crest (22), Crombie also discloses the optional use of other shaped crests (col.4, lines 30-35). A flat crest is known in the screw art to be a common crest shape (see as evidence, Simon et al. US 5,951,560) and would have been an obvious substitution of change of shape from the rounded crest shape. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966).

Claims 42, 44, and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Persoon's (US 5,683,460, cited previously) in view of Simon et al. (US 5,951,560, cited previously). Persoon's discloses a medical implant and method of forming the medical implant substantially as claimed (see above). Persoon's discloses a body (102) having a recessed engagement and a bore used for implantation and guiding into bone (col.4, lines 2-8), however does not show details of the recess and bore (the claimed hexagonal, cylindrical and countersunk is not shown). Simon teaches in the same field of medical implants (specifically bone screws similar to Persoon's), the use of a hexagonal, cylindrical, and countersunk recess (seen in figs.2, 3), for the purpose of guiding and implanting the medical implant into bone just as Persoon's. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Simon's specific recess structure (hexagonal, cylindrical, and countersunk) with Persoon's recitation of a recessed engagement since it would be common sense to use a

known engagement in the art (Simon's) with the screw of Persoon's which discloses use of engagement structures.

Claims 67-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zdeblick et al. (US 2004/0097928 A1, cited previously) in view of Kohrs et al. (US 5,897,593, cited previously). Zdeblick discloses a medical device (10; fig.2-8) and method of implanting the device into the sinus tarsi (P0066) the device comprising a body (11) having a first end (13), second end (12), at least one continuous and uninterrupted thread (19; traverses a portion of the length, near end 12) including a crest with a flat surface (see fig.2, 8; truncated, P0036) having a constant thread height (thread 19 has a constant height; 1 mm, P0036) and helically traversing the length (Zdeblick's thread 19 traverses the length-it is noted that the claims do not require the thread to transverse the entire length), the length extending from the first end to the second end (see figs), a leading and trailing flank (sides of thread 19) inclined away from the ends (appears in fig.3, 5 to be inclined away from the ends in the longitudinal direction and definitely in the radial direction) a recessed engagement in the first end (hex recess, P0040), a bore extending through the body (15), and the body tapering from the first to second end (see fig.2, 8). Zdeblick discloses the device substantially as claimed, however has not shown the detail of the hex recess engagement, and it is unclear whether the bore connects with the recess or not, since it is not illustrated in the figures. Kohrs teaches in the same field of medical implants as Zdeblick, a body having a recessed engagement (40) wherein the bore (hollow) extends from the recessed engagement to the second end (see fig.5; this is not clear in the Zdeblick patent whether the structures are connected). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Zdeblick's implant having a recited bore and recess

(details not shown) with Kohr's teaching of an example of how recessed engagements and bores may be oriented (bore extending from the engagement to the second end) since it would provide predictable result and be common sense to use Kohr's particular engagement bore orientation with Zdeblick's device since Zdeblick has disclosed use of such features.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERYL MILLER whose telephone number is (571)272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cheryl Miller/
Examiner, Art Unit 3738

/Corrine M McDermott/
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